IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. BASIC RESET and BIOGENYX, sole proprietorships, and FRED R. KAUFMAN III and KIMBERLY KAUFMAN, individuals, Defendants.	)	**COMPLAINT FOR PERMANENT INJUNCTION** Civil No. _____

COMPLAINT

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin Basic Reset and Biogenyx, sole proprietorships (together, "Basic Reset/Biogenyx" or the "company") and Fred R. Kaufman III and Kimberly Kaufman, individuals (collectively, "Defendants") from:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343;

C. Violating 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343, while such articles are held for sale after shipment of one or more of their components in interstate commerce; and

D. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce a device, as defined in 21 U.S.C. § 321(h), that is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) and misbranded within the meaning of 21 U.S.C. § 352(o).

2. Defendants label and distribute various types of products, including drugs, dietary supplements, and a device. Defendants distribute their products to consumers nationwide from a facility in Hendersonville, Tennessee.

3. Certain of Defendants' products are drugs under the Act because they are intended for use in diagnosing, curing, mitigating, treating, or preventing disease, such as inflammation, chronic diarrhea, bacterial infections, head lice, and allergies, or because they are intended to affect the structure or function of the body, such as toning muscles. Defendants' drugs are unapproved new drugs because they are not generally recognized as safe and effective, not approved by FDA, and not exempt from the approval requirements.

4. Defendants' dietary supplements are adulterated because they are prepared, packed, or held under conditions that are not in conformance with the current good manufacturing practice

regulations for dietary supplements that are intended to ensure the quality of dietary supplements. In addition, some of Defendants' dietary supplements are misbranded because their labels do not contain information required by law.

5. Defendants distribute a medical device that is adulterated because there is no approved application for premarket approval on file with FDA and it does not fall within an exemption from this requirement, and misbranded because Defendants failed to notify FDA of their intent to introduce the device into interstate commerce for commercial distribution.

6. Beginning in 2012, FDA made Mr. Kaufman aware that he was violating the Act, ultimately sending a Warning Letter in 2016. Despite repeated promises to fix the problems, Defendants have not done so. Accordingly, the United States now seeks a permanent injunction to bring Defendants' operations into compliance with the law.

Jurisdiction and Venue

7. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a), 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

8. Venue in this District is proper under 28 U.S.C. § 1391(b) and (c).

Defendants

9. Defendant Basic Reset/Biogenyx is composed of two sole proprietorships, Basic Reset and Biogenyx. Mr. Kaufman registered both sole proprietorships with the State of Tennessee on April 29, 2019. Mr. Kaufman previously operated Basic Reset and Biogenyx as Tennessee corporations, Basic Reset Inc. and Biogenyx, Inc. Mr. Kaufman dissolved Basic Reset Inc. and Biogenyx, Inc. on April 30, 2019, and the corporations were terminated on May 17, 2019, and May 23, 2019, respectively. Basic Reset/Biogenyx does business at 260 W. Main Street,

Suites 103 and 106D, Hendersonville, Tennessee 37075 (the "Facility"), within the jurisdiction of this Court.

10. Fred R. Kaufman III is the sole proprietor of Basic Reset/Biogenyx, and had been the president and owner of Basic Reset, Inc. and Biogenyx, Inc. He is the most responsible person at the company and handles everything outside of customer service, including but not limited to, website maintenance, product inquiries, finances, contract manufacturer communications, and has the ability to hire and fire employees. Mr. Kaufman performs his duties at the Facility, within the jurisdiction of this Court.

11. Kimberly Kaufman launched Basic Reset, Inc. with Mr. Kaufman in 2015. *See* About Us, Basic Reset, https://www.basicreset.com/aboutus (last visited July 24, 2019). Prior to the dissolution of Basic Reset, Inc. and Biogenyx, Inc. in April 2019, Ms. Kaufman served as the treasurer for these corporations. Her duties at Basic Reset/Biogenyx include banking, assisting distributors, and approving labels. She performs some of her duties at the Facility, within the jurisdiction of this Court.

12. Basic Reset/Biogenyx is an own label distributor of various types of products, including drugs, dietary supplements, and a device. Basic Reset/Biogenyx's products include, but are not limited to, AquaLyte, Bee Gold, Beta Factor, Body Mass Reset, CBD Reset, Dino-Min, Earth Wash, Energy FX, GH-C, Ionyte, Mello-Tonin, Miracle Facelift Masque, Nuovi Firming Masque, Nuovi Skin Toner, pH-FX, Q-min, SlimUp, TrimUp, and Vibrant Energy Drink.

13. Basic Reset/Biogenyx uses several different contract manufacturers to manufacture the products it distributes. Some of Defendants' products arrive pre-labeled from contract manufacturers; however, Defendants also label many of their products in-house.

14. Defendants receive their products from out-of-state contract manufacturers, including from New Mexico and Florida. Defendants distribute their products to customers in various states, including Arizona, Georgia, and Maryland.

15. Basic Reset/Biogenyx operates as a multi-level marketer. Basic Reset/Biogenyx provides each "affiliate" with a website (affiliate name.basicreset.com). The websites for the affiliates, according to Mr. Kaufman, are maintained by Basic Reset/Biogenyx. Basic Reset/Biogenyx also maintains a company website (www.basicreset.com), which is registered to Mr. Kaufman and makes representations about Defendants' products for the treatment of a variety of diseases and/or for use in affecting the structure or function of the body. The company website contains an online store where consumers can purchase Defendants' products directly. Consumers may also purchase products by calling Basic Reset/Biogenyx's office. In addition to the company website, there are several additional websites, such as www.aqualyte.info, www.beegold.info, www.betafactor.info, www.biogenyx.info, www.cbd-reset.info, www.dino-min.info, www.earthwash.info, www.gh-c.info, www.inonyte.info, www.mello-tonin.info, www.nuovi.info, www.ph-fx.info, www.slimupnow.info, and www.trimup.info, which are registered to Mr. Kaufman and include representations about Defendants' products.

Defendants' Violations of the Act

Unapproved New Drugs

16. A product is a drug within the meaning of the Act if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C).

17. Because a product's intended use determines whether it is a drug, a product that falls within the Act's dietary supplement definition may also meet the Act's drug definition if it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. *See* 21 U.S.C. § 321(ff).

18. The Act defines "label" as, *inter alia*, "a display of written, printed, or graphic matter upon the immediate container of any article," 21 U.S.C. § 321(k), and "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

19. Defendants cause many of their products to be drugs within the meaning of the Act because they make claims on their labeling establishing that their products are intended for use in the cure, mitigation, treatment, or prevention of disease ("disease claims").

20. In addition, Defendants cause some of their products (e.g., Nuovi Skin Toner and Nuovi Firming Masque) to be drugs within the meaning of the Act because they make claims on their labeling establishing that their products are intended to affect the structure or function of the body ("structure/function claims").

21. FDA reviewed Defendants' labeling in July 2019 and identified disease claims and structure/function claims, including, but not limited to, the following:

A. Bee Gold: "it can seem like a genuine miracle for people suffering with allergies . . . like myself. Bee pollen was the first dietary supplement I took, after suffering with allergies for 19 years. Finally, for the first time in my life, I felt wonderful, and was able to stop taking allergy shots.";

B. CBD Reset: "been proven to have many health benefits in the areas of . . . chronic pain, inflammation," "I have severe back and neck stiffness from 2 car wrecks, and have

undergone 4 disc replacements and fusion. Nothing I took helped, including other CBD oils, and I spent most days in bed. Starting with Day 1of Reset 2400, the stiffness was almost completely gone! I am mobile again.";

C. Dino-Min: "can help support the body's natural defenses to better deal with such things as: Chronic diarrhea, chronic constipation, gas and bloating Leaky gut syndrome (particles entering the blood that shouldn't) Inflammatory bowel disorders Candida (yeast) overgrowth Bacterial infections Common colds and flu Inflammation throughout the body Autoimmune reactions (immune system attacks the body) Candida (yeast) overgrowth," "Helps support elimination of toxins and heavy metals," "Helps support normal response to pain";

D. Earth Wash: "get rid of head lice";

E. Ionyte: "Helps sooth [sic] cuts, burns, bruises, insect bites and stings";

F. Mello-Tonin: "Helps protect against electromagnetic radiation";

G. Nuovi Firming Masque: "facelift in a bottle," "helps tone the underlying muscles," "helps decrease skin damage," "helps combat acne, inflammation";

H. Nuovi Skin Toner: "helps to soothe cuts, burns, bug bites, bruises, sunburn, and sore muscles";

I. pH-FX: "May Help Support: . . . Body's ability to fight inflammation"; and

J. SlimUp: "helps support . . . healthy cholesterol levels," "helps to support management of inflammation."

22. FDA reviewed Defendants' labeling in March 2019 and identified disease claims and structure/function claims, including but not limited to the following:

A. AquaLyte: "Helps support healthy cholesterol, heart cells, and helps regulate blood sugar," "I had a rash on my back and ankles. The ointments and dermatologist didn't help.

But after just 7 days on AquaLyte the rash was almost gone," "For 15 yrs. I suffered with stomach pain, gas, and tenderness. After 2 days on AquaLyte all the pain was gone and it never came back";

B. Body Mass Reset: "reduces constipation," "helps relieve inflammation of urinary tract," "helps cleanse the body of parasites";

C. GH-C: "A 2009 study out of Auburn University discovered that curcumin is literally 400 times more potent than Metformin (a common diabetes drug) in activating AMPK which helps support healthy insulin sensitivity," "This past year Phytotherapy Research published the results of an amazing study showing curcumin was as effective as Prozac in helping support the body to manage depression";

D. Miracle Facelift Masque: "tightens . . . facial muscles"; and

E. Q-min: "CoQ10 has been used in medical practices for decades, especially in the case of supporting the medical treatment of heart problems."

23. As of July 2019, the products identified in Paragraph 22 no longer appear on Defendants' company website.

24. The claims described in Paragraphs 21 and 22 above demonstrate that these products are drugs because they are intended: (a) to cure, mitigate, treat, or prevent diseases, including inflammation, chronic diarrhea, bacterial infections, head lice, and allergies; and/or (b) to affect the structure or function of the body by, among other things, toning muscles. *See* 21 U.S.C. § 321(g)(1)(B) and (C).

25. A drug is a "new drug" if "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed,

recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a product to be deemed "generally recognized as safe and effective" ("GRAS/E"), it must have substantial evidence of safety and effectiveness. *See* 21 U.S.C. § 355(d). If it is an over-the-counter ("OTC") drug, the product must comply with a monograph established pursuant to an FDA regulation. 21 C.F.R. § 330.1.

26. Defendants' drugs listed in Paragraphs 21 and 22 above lack substantial evidence of safety and effectiveness. There are no published adequate and well-controlled investigations to show that these drugs are GRAS/E for any use and, therefore, qualified experts cannot come to a consensus opinion concerning the effectiveness of these products.

27. Because Defendants' drugs are not GRAS/E, they are new drugs.

28. A drug that is a "new drug" within the meaning of the Act is prohibited from being introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application or abbreviated new drug application for that drug, or the drug is exempt from approval under an investigational new drug application. *See* 21 U.S.C. § 355(a), (b), (i), and (j).

29. FDA searched its records and found no new drug applications, abbreviated new drug applications, or investigational new drug applications for Defendants' new drugs listed in Paragraphs 21 and 22 above. Moreover, Defendants' drugs do not conform to the OTC monograph set forth in 21 C.F.R. § 330.1, or any other OTC drug monograph. Therefore, Defendants' products are unapproved new drugs within the meaning of the Act, 21 U.S.C. § 355(a).

30. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i).

Adulterated Dietary Supplements

31. The Act defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of [any of them]." 21 U.S.C. § 321(ff). A dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." *Id.*

32. Many of Defendants' products, including AquaLyte, Bee Gold, Beta Factor, Body Mass Reset, Dino-Min, GH-C, Ionyte, Mello-Tonin, SlimUp, TrimUp, and Vibrant Energy Drink fall within the Act's definition of a dietary supplement, because they are not represented for use as a conventional food or as a sole item of a meal, they each contain at least one ingredient that is a "dietary ingredient," as defined in 21 U.S.C. § 321(ff), and they are labeled as dietary supplements.

33. The Act deems a dietary supplement to be adulterated if it is not prepared, packed, or held in conformance with the current good manufacturing practice regulations for dietary supplements set forth at 21 C.F.R. Part 111 ("Dietary Supplement CGMP"). 21 U.S.C. § 342(g)(1).

34. The Dietary Supplement CGMP regulations are designed to ensure the quality of dietary supplements. These regulations apply to any person who manufactures, packages, labels, or (subject to an exception not relevant here) holds dietary supplements. These regulations require such persons to control all aspects of their processes and procedures to ensure compliance with

established specifications for identity, purity, strength, composition, and limits on certain types of contamination.

35. FDA investigators inspected Defendants' Facility between October 30 and November 7, 2017 (the "October 2017 Inspection"). The October 2017 Inspection established that the dietary supplements Defendants distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, or held in a manner that does not conform to Dietary Supplement CGMP.

36. During the October 2017 Inspection, FDA investigators documented numerous deviations from the Dietary Supplement CGMP regulations, including but not limited to:

A. Failure to establish specifications to assure that the products they receive for labeling as dietary supplements are adequately identified and consistent with the purchase order (*see* 21 C.F.R. § 111.70(f));

B. Failure to establish specifications for the labeling of their dietary supplements, including specifications to ensure accuracy during the labeling process (*see* 21 C.F.R. § 111.70(g));

C. Failure to establish specifications for their labels (*see* 21 C.F.R. § 111.70(d));

D. Failure to establish and follow written procedures that specify responsibilities for quality control (*see* 21 C.F.R. § 111.103);

E. Failure to identify each unique lot within each shipment of received product in a manner that allows Defendants to trace the lot to the supplier, the date received, the name of the received product, the status of the received product (e.g., quarantined, approved, or rejected), and to the product that Defendants labeled and distributed as dietary supplements (*see* 21 C.F.R. § 111.165(d)(1));

F. Failure to establish and follow written procedures to review and investigate product complaints (*see* 21 C.F.R. § 111.570(b)(2));

G. Failure to make and keep records of any material review and disposition decision on a returned dietary supplement (*see* 21 C.F.R. § 111.535(b)(2)); and

H. Failure to prepare batch production records that document labeling operations at the time Defendants are labeling their products (*see* 21 C.F.R. § 111.260(k)).

37. Defendants violate 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, or held under conditions that do not meet the Dietary Supplement CGMP regulations, 21 C.F.R. Part 111.

38. Defendants violate 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Misbranded Dietary Supplements

39. The Act deems a dietary supplement to be misbranded unless its label or labeling, among other things: correctly reports the serving size; bears nutrition information in a Supplement Facts panel; properly declares dietary ingredients; provides the name of individual ingredients; declares the percent daily value of ascorbic acid; identifies the product by using the term "dietary supplement"; and includes a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event with the dietary supplement. 21 U.S.C. § 343(i)(2), (q)(1)(A), (q)(5)(F), (s)(2)(B), and (y).

40. Several of Defendants' dietary supplements are misbranded within the meaning of the Act, 21 U.S.C. § 343. For example,

A. The labels for Bee Gold, Dino-Min, and TrimUp incorrectly state their serving size in violation of 21 U.S.C. § 343(q)(1)(A), 21 C.F.R. §§ 101.9(b) and 101.12(b);

B. The labels for Bee Gold and Vibrant Energy Drink fail to bear a Supplement Facts panel in violation of 21 U.S.C. § 343(q)(5)(F), 21 C.F.R. § 101.36; and

C. The label for Bee Gold improperly declares dietary ingredients that, because they are not present or are present in amounts that can be declared as zero, should not be included on the label in violation of 21 U.S.C. § 343(q)(5)(F), 21 C.F.R. §§ 101.36(b)(2) and 101.9(c).

41. As of October 2017, Defendants held for sale and/or distributed additional products that were misbranded within the meaning of the Act, 21 U.S.C. § 343, as follows:

A. The AquaLyte label declared "Coral Minerals," but failed to list each individual ingredient in violation of 21 U.S.C. § 343(i)(2), 21 C.F.R. §§ 101.4(a) and 101.36(c)(2);

B. The label for AquaLyte failed to declare the percent daily value of ascorbic acid, in violation of 21 U.S.C. § 343(q)(5)(F), 21 C.F.R. §§ 101.36(b)(2) and 101.9(c)(8)(iv);

C. The label for Body Mass Reset failed to consistently identify the product as a dietary supplement as part of the statement of identity in violation of 21 U.S.C. § 343(s)(2)(B), 21 C.F.R. § 101.3(g); and

D. The label for Body Mass Reset failed to include a street address or phone number through which the responsible person may receive a report of a serious adverse event, in violation of 21 U.S.C. § 343(y).

42. As of July 2019, the products identified in Paragraph 41 no longer appear on Defendants' company website.

43. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements) that are misbranded within the meaning of 21 U.S.C. § 343.

44. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) to become misbranded within the meaning of 21 U.S.C. § 343 while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Adulterated Device

45. The Act defines a "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory which is . . . *intended* for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man . . . or intended to affect the structure or any function of the body of man . . . and which does not achieve its primary intended purposes through chemical action . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h) (emphasis added).

46. Energy FX is "a highly energized, non-toxic (safe enough to drink) liquid inside a pendant that is to be worn as a necklace, carried in a pocket, or attached to your pet's collar." 100-3B Energy FX-Sleek Stainless Steel for Adult, Kids, and Pets, Basic Reset http://www.basicreset.com/index.php?getpage=store&getsec=catalog&page=item&itemid=80&theme=1&xpage=category (last visited July 24, 2019) ("Energy FX Online Catalog Listing").

47. Energy FX is a device within the meaning of the Act, 21 U.S.C. § 321(h), because it is intended for use: (a) in the cure, mitigation, treatment, or prevention of disease, including but not limited to leukemia; and (b) to affect the structure or function of the body of man by, among other things, "strengthen[ing] [consumers] natural bio-energy keeping [consumers] strong against

the onslaught of EMF waves (electromagnetic frequency) produced from electrical devices and Wi-Fi." Energy FX Online Catalog Listing. Additionally, Energy FX does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and is not dependent upon being metabolized, but achieves its primary intended purposes by creating a "Protective Shield Against Electromagnetic Frequencies." *Id.*

48. Defendants' labeling includes the following claims related to Defendants' Energy FX:

A. "[S]trengthen your natural bio-energy, keeping you strong against the onslaught of EMF waves (electromagnetic frequency) produced from electrical devices and Wi-Fi.";

B. "Even if you don't 'feel' any different wearing Energy FX, you can rest assured that you are being protected. Many have reported . . . a decrease in pain."; and

C. "Because of the possible link to childhood leukemia Electormagnetic [sic] Frequencies have been classified as possible carcinogens in 1998 by the National Environmental Health Institute (NIEHS) and in 2001 by the International Agency for Research on Cancer (IARC) of the World Health Organization."

49. The claims described in Paragraph 48 above demonstrate that Defendants' Energy FX is a device within the meaning of the Act because it is intended to cure, mitigate, treat, or prevent diseases or affect the structure or any function of the body of man and achieves its primary intended purposes not through chemical action or by being metabolized.

50. The Medical Device Amendments of 1976 classified medical devices into one of three categories—Class I, II, or III. 21 U.S.C. § 360c. A device's class determines the type of regulatory controls to which it is subject and any review and marketing authorization it must go through prior to marketing.

51. A Class III device is adulterated if: (1) it is required to have in effect an approved application for premarket approval under 21 U.S.C. § 360e(a); (2) there is no FDA-approved application for premarket approval in effect for such device; and (3) it is not exempt from premarket approval as an investigational device under 21 U.S.C. § 360j(g). 21 U.S.C. § 351(f)(1)(B).

52. Devices that are introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, are automatically classified into Class III as a matter of law. 21 U.S.C. §§ 360c(f)(1) and 360e(a). Those devices remain in Class III and require premarket approval unless and until FDA, by written order, reclassifies the devices into Class I or II or FDA issues a written order finding the device to be substantially equivalent to a legally marketed predicate device. 21 U.S.C. § 360c(i).

53. FDA determines whether new devices are substantially equivalent to predicate devices by means of the premarket notification procedures set out in 21 U.S.C. § 360(k). *See also* 21 CFR Part 807, Subpart E. In general, manufacturers are required to submit a 510(k) premarket notification for any device that is being introduced into commercial distribution for the first time. 21 C.F.R. § 807.81(a)(1).

54. Alternatively, a sponsor of a device introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, with low to moderate risk may submit a direct *de novo* classification request to FDA to determine whether the device is appropriate for classification into Class I or II if there is no legally marketed predicate device and the sponsor provides information demonstrating that general controls, or a combination of general controls and special controls, are sufficient to provide a reasonable assurance of safety and effectiveness of the device. 21 U.S.C. § 360c(f)(2).

55. Defendants' device, Energy FX, is a Class III device by law because it is a device intended for human use and was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and it does not meet the exemptions set forth in 21 U.S.C. § 360c(f)(1).

56. Defendants' device does not have an approved application for premarket approval pursuant to 21 U.S.C. § 360e(a) or an effective investigational device exemption under 21 U.S.C. § 360j(g).

57. Defendants' device, Energy FX, is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B).

58. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of a device that is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B).

Misbranded Device

59. A device is deemed to be misbranded if a premarket notification for such device was not provided as required under 21 U.S.C. § 360(k). 21 U.S.C. § 352(o).

60. Premarket notification is required for any device that is, *inter alia,* being introduced into commercial distribution for the first time. 21 C.F.R. § 807.81(a)(1).

61. The premarket notification required under 21 U.S.C. § 360(k) is deemed satisfied when a premarket approval application or a *de novo* classification request is pending before FDA. 21 C.F.R. § 807.81(b).

62. Defendants did not submit a premarket notification to FDA for the device that they have been introducing and delivering for introduction, and/or causing the introduction or delivery for introduction, into interstate commerce for commercial distribution.

63. Defendants' device is misbranded within the meaning of 21 U.S.C. § 352(o).

64. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce a device that is misbranded within the meaning of 21 U.S.C. § 352(o).

Previous Violations

65. Defendants have previously been in violation of the Act, as documented by FDA investigators during inspections conducted from April 25–27, 2012 (the "2012 Inspection"), March 2–7, 2016 (the "2016 Inspection"), and March 20–27, 2017 (the "March 2017 Inspection").

66. During these inspections, FDA investigators observed Dietary Supplement CGMP deviations many of which were the same or similar to CGMP deviations observed during FDA's October 2017 Inspection including, but not limited to: the failure to establish specifications, failure to establish a quality control system, and the failure to identify each unique lot within each shipment of received product. Additionally, during the 2012 inspection, FDA investigators identified potential drug claims on Defendants' labeling.

67. FDA repeatedly warned Mr. Kaufman and the company about many of their ongoing violations. At the close of each inspection, FDA investigators issued a List of Inspectional Observations ("Form FDA 483") to, and discussed the observations with, Mr. Kaufman.

68. On July 1, 2016, FDA issued a Warning Letter to Mr. Kaufman and Basic Reset/Biogenyx, informing them that they were introducing into interstate commerce adulterated dietary supplements and misbranded dietary supplements, and described multiple Dietary Supplement CGMP violations and ways in which they had misbranded some of their dietary supplements. The Warning Letter also informed them that they were introducing into interstate commerce unapproved new drugs (AquaLyte, Bee Gold, Beta Factor, and Ionyte).

69. Mr. Kaufman has repeatedly promised to correct the Dietary Supplement CGMP deficiencies observed by FDA. Specifically, in a March 18, 2016 letter, Mr. Kaufman stated that within 90–120 days he would implement resolutions to all observations cited in the 2016 Form FDA 483. But, as discussed above, FDA investigators observed many of the same Dietary Supplement CGMP deficiencies during subsequent inspections. Similarly, in response to the Warning Letter, Mr. Kaufman sent FDA a letter dated July 25, 2016, stating that he had, among other things, "revised [Basic Reset/Biogenyx's] website to remove any reference to medical claims" and "revised product labels to meet requirements." However, during the October 2017 Inspection, FDA found many of the same or similar dietary supplement misbranding issues still ongoing. Additionally, as recently as July 2019, Defendants are still making disease claims and structure/function claims for many of their products. Similarly, in an April 14, 2017, letter to FDA, Mr. Kaufman stated that he had reached out to a law firm that would help him address all the observations cited in the March 2017 Form FDA 483 within the next thirty days. But, as mentioned above, FDA investigators observed many of the same or similar violations during the October 2017 Inspection. Defendants have not responded to the October 2017 Form FDA 483.

70. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered or introduction, into interstate commerce articles of food (including but not limited to dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343 and a device that is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) and misbranded within the meaning of 21 U.S.C. § 352(o); and

C. Violating 21 U.S.C. § 331(k), by causing articles of food (including but not limited to dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343, which such articles are held for sale after shipment of one or more of their components in interstate commerce;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce any drugs, articles of food (including dietary supplements), or devices unless and until:

A. An approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drug; or Defendants have removed from (1) labeling; (2) promotional

materials; (3) websites owned, controlled by, or related to Defendants; and (4) any other media over which Defendants have control, all representations about the intended use(s) of Defendants' products that cause such products to be drugs as defined by the Act;

B. Defendants' facilities, methods, processes, and controls used to receive, label, hold, and distribute dietary supplements are established, operated, and administered in conformity with Dietary Supplement CGMP and the Act, in a manner acceptable to FDA;

C. Defendants' dietary supplement labeling complies with 21 U.S.C. § 343 and applicable regulations, in a manner acceptable to FDA; and

D. Defendants' device is the subject of an approved application for premarket approval under 21 U.S.C. § 360e(a), the subject of an investigational device exemption under 21 U.S.C. § 360j(g), the subject of a cleared premarket notification under 21 U.S.C. § 360(k), or the subject of a grant of *de novo* classification from FDA under 21 U.S.C. § 360c(f)(2); or Defendants have removed all representations about the intended use(s) of Defendants' product that causes such product to be a device as defined by the Act from (1) labeling; (2) promotional materials; (3) websites owned, controlled by, or related to Defendants; and (4) any other media over which Defendants have control;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business, and all records relating to the receipt, labeling, holding, and distribution of all of Defendants' products, including drugs, articles of food (including dietary supplements), and devices, to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 26th day of August, 2019.

Respectfully submitted,

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